

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 34

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte ROBERT E. GARFIELD,  
KRZYSZTOF CHWALISZ,  
RADOSLAW BUKOWSKI,  
and CHANDRA YALLAMPALLI

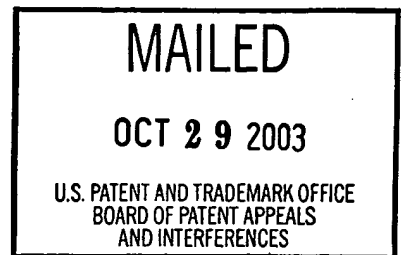
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Appeal No. 2003-1008  
Application No. 09/121,849

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HEARD: October 9, 2003

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Before WINTERS, LORIN, and SCHEINER, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

**REMAND TO THE EXAMINER**

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 14, 17-19 and 29, all the claims pending in the application.<sup>1</sup>

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<sup>1</sup> Pursuant to 35 U.S.C. § 6(b), we review the adverse decision of the examiner. In doing so, we have considered the record, including:

- Final Rejection (paper no. 8);
- Advisory Action (paper no. 13);
- Rejection (paper no. 20);
- Second Final Rejection (paper no. 23);
- Brief (paper no. 26);
- Examiner's Answer (paper no. 27); and,
- Reply Brief (paper no. 28).

Claim 14, the sole independent claim, is illustrative of the claims on appeal and reads as follows:

14. A pharmaceutical composition comprising an admixture of effective amounts of:
- (a) a progestin and
  - (b) a nitric oxide synthesis substrate, a nitric oxide donor or both, and,
  - (c) at least one of a cyclooxygenase inhibitor, a PGI<sub>2</sub>-mimetic, a thromboxane (TXA<sub>2</sub>) inhibitor, a compound possessing PGI<sub>2</sub>-agonistic and TXA<sub>2</sub>-inhibiting properties, a compound possessing TXA<sub>2</sub>-antagonistic and PGI<sub>2</sub>-mimetic activities, and a TXA<sub>2</sub>-antagonistic, in amounts effective to ameliorate the symptoms of preeclampsia accompanied or unaccompanied by preterm labor in a pregnant female mammal, dysmenorrhea, or functional uterine bleeding or hemorrhaging.

The reference relied upon by the examiner is:

Harrison et al. (Harrison)

5,508,045

Apr. 16, 1996

The rejection is:

Claims 14, 17-19 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harrison.

#### DISCUSSION

Claims 14, 17-19 and 29 stand or fall together (see Answer, p. 3 and Brief, p. 3). Accordingly we focus our attention on claim 14.

The claimed invention is directed to a composition for use in the treatment of preeclampsia comprising an admixture of effective amounts of three substances (see claim 14 reproduced supra).

In a nutshell, the examiner takes the position that Harrison teaches each of the claimed substances and that

[i]t would have been obvious that one of ordinary skilled [sic, skill] in the art would have reasonably expectation of success [sic, ?] that any combination of agents, which includes the combination of nitric oxide donor with the two additional tocolytic agents of progestin and aspirin, would be within the scope of the prior art invention for controlling and managing the same symptoms as claimed, thus rendering the claimed pharmaceutical composition unpatentable over the art.

Answer, p. 8. Appellants argue that Harrison teaches numerous substances without giving any direction to one of ordinary skill to select the three substances claimed.

... [I]t is clear that Harrison suggests very generically an infinite set of possible combinations. Such a broad statement does not render obvious any particularly subsumed combination of specific compounds which may happen to satisfy the recitations of the claims here. Without more, there can be no motivation to make the selections leading to the claimed invention.

Brief, p. 4.

We have carefully reviewed the positions put forward by the examiner and appellants but we cannot proceed to review the merits of the rejection because we find that there is a question as to whether Harrison is available as prior art against the claimed invention.

According to the record,

1. the involved application, filed on July 24, 1998, was filed as a divisional application under 37 CFR §1.53(b) of prior application Serial No. 08/092,426, filed on July 16, 1993 (see Paper No. 21);
2. the reference relied upon by the examiner, the Harrison patent, has a filing date of February 18, 1994, and was granted on April 16, 1996, and there is an indication on the patent that the patent is a continuation-in-part of application Serial No. 959,006, filed October 9, 1992, now abandoned;
3. the Answer (p. 3) indicates, under the heading "Prior Art of Record," that the aforementioned Harrison patent has a filing date of "2-1994;" and,
4. the Answer (p. 3) indicates, under the heading "Grounds of Rejection," that "Harrison et al[.] U.S. 5,508,045 obtains benefit of the earlier filing date for the subject matter relied upon for the rejection."

The Answer (fact 3. supra) acknowledges that Harrison has a filing date of February 18, 1994. However, if Harrison is limited to a filing date of February 18, 1994, then Harrison would not be available as prior art against the claimed invention because appellants' involved application has been accorded the benefit of a filing date, i.e., July 16, 1993, which is earlier in time.

Harrison could be available as prior art under 35 U.S.C. § 102(e) if it is entitled to the October 9, 1992 filing date of the application Serial No. 959,006 indicated on the patent. However, there is no evidence that the issue of the availability of Harrison as prior art was ever considered. The examiner does state in the Answer (p. 3) that "Harrison et al[.] U.S. 5,508,045 obtains benefit of the earlier filing date for the subject matter relied upon for the rejection." But while this suggests that the examiner was aware of the issue, albeit belatedly, there is no analysis explaining how the examiner reached that conclusion.

Harrison is a continuation-in-part of parent application Serial No. 959,006 and must be accorded the filing date of the parent application in order to constitute legally available prior art against the instant claims. The examiner should explain how he reached the conclusion that Harrison, a continuation-in-part of application Serial No. 959,006, is entitled to the filing date of that application and give appellants an opportunity to rebut that conclusion. Before drafting that explanation, the examiner is advised to review Ex part Ebata, 19 USPQ2d 1952 (Bd. Pat. App. & Int. 1991) where the threshold question of whether a patent cited against an applicants' claims was legally available prior art under 35 U.S.C. §102(e) is fully addressed. The Manual of Patent Examining Procedure (MPEP) 2136.02 is also relevant.

In reviewing, on appeal, a PTO Board's findings and conclusions, the Federal Circuit has stated that "[f]or judicial review to be meaningfully achieved within these strictures<sup>2</sup>, the agency tribunal must present a full and reasoned explanation of its decision. The agency tribunal must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application of the law to the found facts." In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432-3 (Fed. Cir. 2002). "The agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action." Ibid. at 277 F.3d 1346, 61 USPQ2d 1435. "Remand for these purposes is required." Ibid. at 277 F.3d 1346, 61 USPQ2d 1436." Since the Board also serves as a board of review, not a de novo examination tribunal (35 U.S.C. § 6(b)), in order for the Board to make a meaningful review of the rejection on appeal, examiner likewise must present a full and reasoned explanation in support of the final rejection. As we have explained above, that has not been done here.

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<sup>2</sup> "5 U.S.C. §706(2) The reviewing court shall—

(2) hold unlawful and set aside agency actions, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

\* \* \* \*

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute;"

In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1433-4 (Fed. Cir. 2002).

Accordingly, for the foregoing reasons, we remand the application to the examiner in charge to obtain clarification of the legal availability of Harrison as prior art against the claimed invention. The course of action that examiner takes to satisfy this remand should include giving appellants an opportunity to respond.

REMANDED

  
SHERMAN D. WINTERS )

Administrative Patent Judge )

  
HUBERT C. LORIN )

Administrative Patent Judge )

) BOARD OF PATENT

) APPEALS AND

  
TONI R. SCHEINER )

Administrative Patent Judge )

) INTERFERENCES

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